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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,226	01/11/2002	Bernd Riedl	BAYER 25A	5076

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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/042,226	RIEDL ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,9-11,13,15,38,39,44-49,53,54,66,67,70,71,73,75,76,78,80,81,83 and 88-121* is/are rejected.

7)☒ Claim(s) *38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 6,7,9-11,13,15,38,39,44-49,53,54,66,67,70,71,73,75,76,78,80,81,83 and 88-121.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/14/2006 has been entered.

Change of Examiner

The examiner assigned to the instant application has changed. The new examiner is James D. Anderson, Ph.D. Contact information is provided at the end of this Office Action.

Status of the Claims

Claims 6-7, 9-11, 13, 15, 38-39, 44-49, 53-54, 66-67, 70-71, 73, 75-76, 78, 80-81, 83, 88-121 are currently pending and are the subject of this Office Action. This is the first Office Action following the Request for Continued Examination filed 6/14/2006.

Notice of Appeal

The Notice of Appeal filed 3/15/2006 is deemed **moot** is view of the withdrawal of the finality of the Office Action mailed 9/14/2005 and the submission of a Request for Continued Examination filed 6/14/2006.

Priority

Priority is claimed to Provisional Application Serial No. 60/367,379 filed on January 12, 2001 (see Amendment filed 5/14/2003).

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed 6/14/2006. Examiner has considered the references cited therein to the extent that each is a proper citation. The cited U.S. Patents were not considered because the inventor and date of publication are missing. Some cited foreign patent documents were not considered because the name of patentee and date of publication are missing. Some cited non-patent literature documents were not considered because a publication date was not provided and in some cases, the citation is incomplete. Please see attached USPTO Form 1449.

Claim Objections

Claim 38 is objected to because of the following informalities: at page 4 of the claims, line 4, claim 38 recites "...or is r NR_aR_b where ...". The "r" preceding NR_aR_b appears to be a typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 13 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 recites the limitation wherein W is "as defined in claim 2". Claim 2 has been cancelled. Thus, the definition of W is not clear and distinct as required by 35 U.S.C. 112, 2nd Paragraph. The metes and bounds of the claimed subject matter are not clear because the substituent "W", as recited in claim 6, is not defined.

Claims 6, 10, 11, 13, 38-39, 44-49, 53-54, 70-71, 75-76 and 80-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claims 38 and 39 recite compounds comprising a substituent designated "R^7". This substituent is not defined in the claims. As such, the metes and bounds of the claimed subject matter are not clear and definite as required by 35 U.S.C. 112, 2nd Paragraph.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 66 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description Rejection.

There is insufficient descriptive support for the genera recited in the claim. Claim 66 recites a method of treatment comprising administering a:

3-tert butyl phenyl urea;

5-tert butyl-2-methoxyphenyl urea;

5-(trifluoromethyl)-2-phenyl urea;

3-(trifluoromethyl)-4-chlorophenyl urea;

3-(trifluoromethyl)-4-bromophenyl urea; or

5-(trifluoromethyl)-4-chloro-2-methoxyphenyl urea.

Other than the compounds of Formula I as disclosed in the specification, the disclosure does not provide adequate written description for these compounds. The substituents that may be present on these compounds are not defined and the disclosure provides no means for the skilled artisan to make these compounds, aside from those whose structure is defined in the disclosure (*e.g.*, compounds of Formula I).

Claim 90 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description Rejection.

There is insufficient descriptive support for the phrase "the treatment of a raf mediated disorder". The claimed methods of treatment fail meet the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. 112, 1st Paragraph. The claimed

methods require the treatment of an unspecified disease or disorder and no evidence indicates that a treatable disease was known to Applicants. In addition, the instant specification does not describe what is meant by the phrase "the treatment of a *raf* mediated disorder". In the absence of some understanding of the conditions to be treated, one of ordinary skill in the art would not have concluded that Applicant was in possession of the claimed methods. Accordingly, these claims fail to comply with the written description requirement.

Regents of the University of California v. Eli Lilly & Co., 119 F. 3d 1559, 1568 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089, 118 S.Ct. 1548 (1980), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1st Paragraph ("Written Description" Requirement) ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, "including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure...." *Enzo Biochem., Inc. v. Gen-Probe.*, 296 F.3d, 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. At 1106 (emphasis added)).

Claims 6-7, 9-11, 13, 15, 38-39, 44-49, 53-54, 66-67, 70-71, 73, 75-76, 78, 80-81, 83, 88-121 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification

in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an Enablement Rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence or absence of working examples,

4) the nature of the invention,

[1] As pointed out by the court in *In re Angstadt*, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) The breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill of those in the art

The invention relates to the treatment of cancerous cell growth mediated by RAF kinase comprising administering one of a multitude of compounds represented by Formula I as recited in claim 38.

The relative skill of those in the art is high, generally that of an M.D. or Ph.D. The artisan using Applicant's invention would generally be a physician with a M.D. degree and several years of experience.

That factor is outweighed, however, by the unpredictable nature of the art. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 166 USPQ 18, at 24 (In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies

inversely with the degree of unpredictability of the factors involved.), *Nationwide Chemical Corporation, et al. v. Wright, et al.*, 192 USPQ 95 (one skilled in chemical and biological arts cannot always reasonably predict how different chemical compounds and elements might behave under varying circumstances), *Ex parte Sudilovsky* 21 USPQ2d 1702 (Appellant's invention concerns pharmaceutical activity. Because there is no evidence of record of analogous activity for similar compounds, the art is relatively unpredictable) *In re Wright* 27 USPQ2d 1510 (the physiological activity of RNA viruses was sufficiently unpredictable that success in developing specific avian recombinant virus vaccine was uncertain). As illustrative of the state of the art, the examiner cites Gura *et al.* (Science, 1997, 278:1041-1042) and Johnson *et al.* (British J. of Cancer, 2001, 84(10):1424-1431).

Gura *et al.*, cited for evidentiary purposes, teaches that researchers face the problem of sifting through potential anticancer agents to find the ones promising enough to make human clinical trials worthwhile and further teach that since formal screening began in 1955, many thousands of drugs have shown activity in either cell or animal models but that only 39 have actually been shown to be useful for chemotherapy (p. 1041, see first and second paragraphs). It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. Also, with regard to unpredictability, Johnson *et al.*, also cited for evidentiary purposes, teach that the *in vivo* activity of 39 different agents in a particular histology in a tumor model did not correlate to activity in the same human cancer. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Further, the

mode of action of anticancer agents is often unknown or very unpredictable and administration of such agents is often accompanied by undesirable side effects.

These articles plainly demonstrate that the art of developing and testing anticancer drugs, particularly for use in humans, is extremely unpredictable, particularly in the case of a single compound or genus of compounds being used to treat any and all cancers.

2. The breadth of the claims

The claims vary in breadth; some (such as claim 38) vary broadly, reciting the treatment of cancerous cell growth mediated by RAF kinase with a broad genus of compounds. Others, such as claim 67, are narrower, reciting specific species of the claimed genus of compounds. All, however, are extremely broad insofar as they disclose the general treatment of cancerous cell growth with the same compounds.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for determining the particular administration regimens (*e.g.*, dosages, timing, administration routes, etc.) necessary to treat all of the various tumors claimed, particularly in humans. The direction concerning treating cancer is found in the specification at pages 95-96, which merely states Applicants' intention to do so by providing a cellular assay and an *in vivo* assay for determining the cell growth inhibitory effect of the claimed compounds. No compounds were actually tested in these assays. Applicants describe formulations at pages 10-13. Doses required to practice their invention are described at

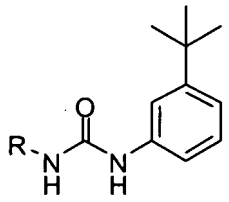
page 13. A 20,000-fold range of doses is recommended (*e.g.*, 0.01 to 200 mg/kg). Since only one substituted phenyl urea as instantly claimed has ever been used to treat any human cancer, how is the skilled physician to know what dose to use for each of these pathologically different cancers and structurally diverse compounds? There are no guidelines for determining the doses needed to treat a carcinoma *vs.* a myeloid disorder *vs.* adenoma (*e.g.*, claim 70). Are the identical doses to be used for treating these unrelated cancers? There is both an *in vitro* cellular assay and an *in vivo* assay described in pages 95-96 (with no data) and it is unclear if these assays correlate to all of the cancers encompassed by the claims. There is no working example of treatment of any cancer in cells, animals or man. The *raf* kinase assay (pages 94-95) provides evidence that some of the present compounds inhibit *raf* kinase. However, inhibition of a receptor does not predictably correlate to clinical efficacy. Thus, there are no working examples correlating inhibition of *raf* kinase with efficacy in the treatment of cancer using the claimed compounds (*i.e.,* Applicants have not shown that inhibition of *raf* kinase activity with a compound of the invention correlates to *in vitro* and/or *in vivo* anticancer efficacy with the same compound).

4. The quantity of experimentation necessary

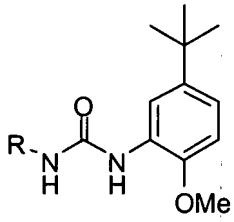
Because of the known unpredictability of the art (as discussed *supra*) and in the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept the assertion that the instantly claimed genus of compounds could be predictably used as a treatment for all cancerous cell growth mediated by RAF kinase as inferred in the claims and contemplated by the specification.

Genentech Inc. vs. Nova Nordisk states, "[A] patent is not a hunting license. It is not a reward for a search but a compensation for its successful conclusion and 'patent protection' is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" (42 USPQ 2d 1001, Fed. Cicuit 1997).

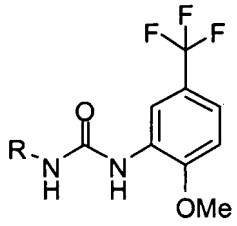
In the instant case, Applicants have presented a general idea that because the instantly claimed compounds inhibit *raf* kinase they must therefore, *a priori*, be useful in the treatment of cancerous cell growth. However, the claims encompass a multitude of compounds (perhaps millions) having a plethora of chemically and biologically distinct substituents. Applicants synthesized 103 compounds with very similar core structures (see Tables 1-7).



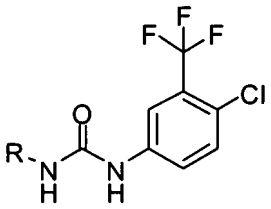
3-*tert*-Butylphenyl Ureas



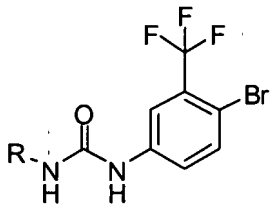
5-*tert*-Butyl-2-methoxyphenyl Ureas



5-(Trifluoromethyl)-2-methoxyphenyl Ureas

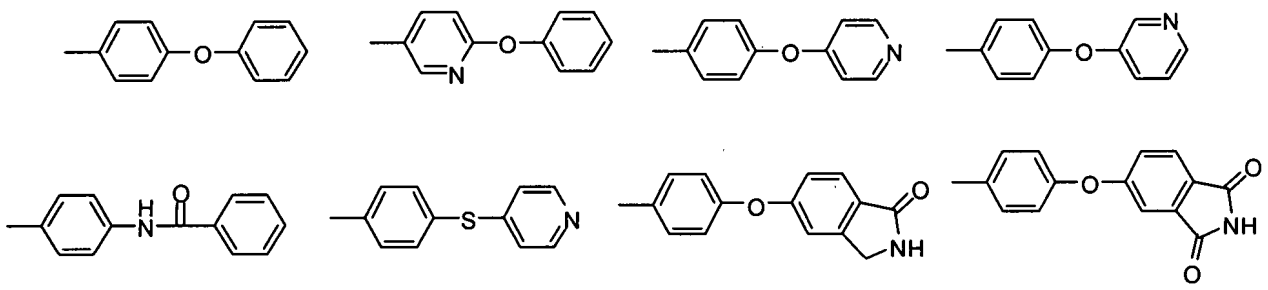


3-(Trifluoromethyl)-4-chlorophenyl Ureas

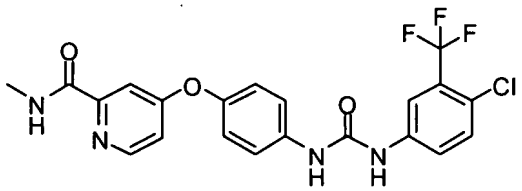


3-(Trifluoromethyl)-4-bromophenyl Ureas

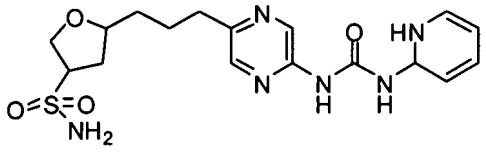
Moreover, the "R" groups in the synthesized compounds only encompass eight substituted and unsubstituted cores.



It is evident that a very small percentage of the claimed compounds were actually synthesized and tested (for *ras* kinase inhibition) by Applicants and all of the synthesized compounds were related in structure. For example, as defined in claim 38, "B" is a substituted or unsubstituted phenyl, pyridyl or pyrimidinyl group. Only phenyl group compounds were synthesized with five different substituents in the same positions. Further, as defined in claim 38, "A is of the formula: -L-(M-L^1)$_q$, where L is a 6 membered aryl moiety or a 6 membered hetaryl moiety bound directly to D, L^1 comprises a substituted cyclic moiety having 5-6 members, q is an integer of from 1-3; and each cyclic structure of L and L^1 contains 0-4 heteroatoms which are nitrogen, oxygen or sulfur" and "wherein L^1 is substituted by at least one substituent which is of -SO_2R_x, -$C(O)R_x$ or -$C(NR_r)R_z$". Only compounds wherein L or L_1 contain nitrogen, q is 1 and L^1 is substituted with -$C(O)R_x$ were synthesized. Thus, the compounds actually synthesized and screened by Applicants do not correlate in scope with the claimed subject matter. For example, the compound of Entry 42 (Table 4) is the drug Sorafenib.



Entry 42 (Sorafenib)
(synthesized and tested)



Compound A
(encompassed by claims but not synthesized or tested)

This compound was synthesized and tested for *raf* kinase inhibition by Applicants. Compound A is a hypothetical compound that is encompassed by the claims. This compound, and compounds like it, have not been synthesized or tested. One skilled in the art would not reasonably expect that Compound A would have similar activity to the compounds synthesized and tested by Applicants. The only common structural feature is the –NH-C(O)-NH- moiety. Given the extremely diverse compounds encompassed by the claims and the limited examples provided in the specification, the skilled artisan cannot predict what structural features (other than those of the compounds actually synthesized) are important for *raf* kinase inhibition. In other words, the structure activity relationship demonstrated in the examples is limited to a very small sub-genus of compounds.

Applicants tested "exemplified" compounds (which compounds were actually tested is not disclosed) for inhibition of *raf* kinase. Applicants state, "[A]ll compounds exemplified displayed IC_{50}s of between 1 nM and 10 μM (page 95, line 8). Conspicuously absent is any disclosure as to what compounds were most effective (1 nM) or least effective (10 μM) at inhibiting *raf* kinase. As such, the skilled artisan is given no guidance or direction with respect to compounds that might be more expected to treat cancerous cell growth versus those that would not be expected to be clinically effective.

Determining if any particular claimed compound would treat any particular cancerous disease state would require synthesis of the compound, formulation into a suitable dosage form, and subjecting it to clinical trials or to testing in an assay known to correlate to clinical efficacy of such treatment. This is undue experimentation given the limited guidance and direction

provided by Applicants. As noted *supra*, even *in vitro* and *in vivo* assays do not always correlate to efficacy in humans and are not generally predictive of clinical efficacy.

Accordingly, the instant claims do not comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-7, 9-11, 13, 15, 38-39, 44-49, 53-54, 66-67, 70-71, 73, 75-76, 78, 80-81, 83, 88-121 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-30, 36 and 48 of copending Application No. 09/777,920. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment recited in the claims of the '920 application encompass administration of the instantly claimed compounds of Formula I.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 6-7, 9-11, 13, 15, 38-39, 44-49, 53-54, 66-67, 70-71, 73, 75-76, 78, 80-81, 83, 88-121 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 62-65 and 67 of copending Application No. 09/948,915. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment recited in the claims of the '915 application encompass administration of the instantly claimed compounds of Formula I.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 6-7, 9-11, 13, 15, 38-39, 44-49, 53-54, 66-67, 70-71, 73, 75-76, 78, 80-81, 83, 88-121 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, 11-13, 15-16 and 80-87 of copending Application No. 09/640,780; claims 15-19 and 28-33 of copending Application No. 09/776,936; claims 74, 81,

87, 93 and 99-116 of copending Application No. 09/993,647; claims 13-21, 23-27, 34-38, 40-43 and 48 of copending Application No. 10/895,985; claim 34 of copending Application No. 10/361,858; claims 40-58 of copending Application No. 10/788,029; claims 16-23 of copending Application No. 10/788,426; and claims 8-18 of copending Application No. 10/789,446. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment recited in the claims of the cited applications encompass administration of the instantly claimed compounds of Formula I.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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April 18, 2007

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PRIMARY EXAMINER